

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF INDIANA
FORT WAYNE DIVISION

RONALD J. MCAFEE,)	
)	
Plaintiff)	
)	
v.)	CIVIL NO. 1:12-CV-417 RLM
)	
MEDTRONIC, INC.,)	
)	
Defendants)	

OPINION AND ORDER

Ronald McAfee sued Medtronic, Inc., a medical device manufacturer, under Indiana's Product Liability Act and common law alleging that he was injured by a defective Medtronic Sprint Fidelis Lead (Model 6949). After Medtronic's motion to dismiss the amended complaint under Fed. R. Civ. P. 12(b)(6) was granted in part and denied in part, Medtronic moved for reconsideration [Doc. No. 32], asking the court to dismiss the remaining state law claims premised on an alleged failure to warn and grant the motion to dismiss in its entirety. For the following reasons, the court grants the motion.

I. DISCUSSION

Medtronic raised two issues on reconsideration, but based its motion on only one: whether the amended complaint sufficiently alleges causation. To state a plausible parallel claim for failure to warn and avoid preemption, Mr. McAfee must allege (and ultimately prove) that: (1) Medtronic violated a federal

requirement applicable to the Sprint Fidelis lead; (2) state law imposes a “genuinely equivalent” requirement; and (3) the federal violation caused his injuries. See Bates v. Dow Agrosiences LLC, 125 S.Ct. 1788, 1804 (2005); Wolicki-Gables v. Arrow Int’l, Inc., 634 F.3d 1296, 1300-01 (11th Cir. 2011) McMullen v. Medtronic, Inc., 421 F.3d 482, 488-89 (7th Cir. 2005). In its ruling on the dismissal motion, the court found that Mr. McAfee had satisfied the first two requirements, but the court didn’t address the third – an error that can be rectified under Fed. R. Civ. P. 54(b).

A.

Mr. McAfee’s failure to warn claim is premised on these allegations:

1. “Under federal law and regulation, Medtronic was under a continuing duty to monitor the [Sprint Fidelis Lead] after premarket approval and to discover and report to the [FDA] any complaints about the performance of the product and any adverse health consequences of which it became aware and that were, or might be, attributable to the product. See 21 C.F.R. Part 803.50, 21 C.F.R. Sec. 820.198(a)(3) (2005) and 21 U.S.C. Sec. 360(i) (2000).” (Amd. Cmplt. ¶¶ 20 and 65).
2. The Conditions of Approval applicable to the lead required that adverse event reports “be filed with the [FDA] within 10 days of the date that Medtronic was informed of the adverse event.” (Amd. Cmplt. ¶ 21).
3. Medtronic failed to comply with that condition and violated federal reporting requirements (21 U.S.C. § 360(i), 21 C.F.R. §§ 803.50 and 814.82(a)(9)), when it received notice of 15 adverse events of inappropriate shocks associated with the Sprint Fidelis Lead in February, April, and May of 2006, but waited until July 10, 2006 to report those adverse events to the FDA. (Amd. Cmplt. ¶¶ 21).
4. “[Medtronic] was or should have been aware no later than March of 2006 that the Medtronic Sprint Fidelis Model 6949 Lead was

inordinately prone to develop fractures causing inappropriate shocks or loss of therapy after implantation in patients, yet failed to give effective notice to the physicians who had previously implanted the product...of the danger of the product.” Amd. Cmplt. ¶ 28.

5. “Such a warning, if given, would have caused such physicians and subsequent patients to consider an alternative product prior to surgical implantation, and to avoid the serious injuries that resulted from implantation of the [Sprint Fidelis Lead].” (Amd. Cmplt. ¶ 29).

6. The Sprint Fidelis Lead implanted in Mr. McAfee on July 21, 2006 and removed on November 22, 2010 was “defective and unreasonably dangerous as a result of inadequate warnings,” in violation of federal and state law, specifically Indiana Code §§ 34-20-2-2 and 34-20-4-2, and was “a producing cause of plaintiff’s injuries and damages.” (Amd. Cmplt. ¶¶ 31, 38, 43, and 45).

7. The failure to report adverse events to the FDA, alone or in combination with other acts or omissions, “proximately caused Plaintiff’s injuries and damages.” (Amd. Cmplt. ¶¶ 66(g) and 67).

[Doc. No. 19].

Medtronic argued in its original brief and on reconsideration that the fifteen adverse event reports on which Mr. McAfee relies to establish causation were filed *before* his lead was implanted and clearly didn’t cause Mr. McAfee and his physician to consider or use an alternative product, so any delay in filing couldn’t have caused his injury. Noting that Mr. McAfee hadn’t presented any other facts which, if true, would establish a causal nexus between the alleged reporting violations and his injuries, Medtronic concluded that Mr. McAfee hadn’t stated a plausible claim for relief based on a failure to warn.

Although Mr. McAfee didn’t address the issue in his response to the motion to dismiss or move to amend his complaint, he now says that the fifteen violations

alleged in paragraph 21 of the amended complaint weren't isolated events, but instead establish a "pattern of late reporting" and a "continuing wrong" that began before his lead was implanted on July 21, 2006 and continued thereafter. He cites in support the results of an internet search he conducted after the motion to reconsider was filed, which showed that the FDA received 166 adverse event reports of "inappropriate shock" between July 1, 2006 and March 1, 2007, one of which involved an event that occurred on July 2, 2006 (before his surgery), but wasn't reported until August 15, 2006 (44 days after Medtronic received notice of the event and 25 days after his surgery). [Doc. No. 38 (Exh. A and B)]. Mr. McAfee believes that there might be more.

Mr. McAfee can't amend his complaint by raising new claims in response to the motion to dismiss, Agnew v. Nat'l Collegiate Athletic Ass'n, 683 F.3d 328, 348 (7th Cir. 2012); Thomason v. Nachtrieb, 888 F.2d 1202, 1205 (7th Cir. 1989), but he can "elaborate on his factual allegations so long as the new elaborations are consistent with the pleadings," and "submit materials outside th pleadings to illustrate the facts [he] expects to be able to prove." Geinosky v. City of Chicago, 675 F.3d 743, 745 n.1 (7th Cir. 2012). *See also* Wigod v. Wells Fargo Bank, N.A., 673 F.3d 547, 555 (7th Cir. 2012); Thomas v. Guardsmark, Inc., 381 F.3d 701, 704 (7th Cir. 2004); Chavez v. Illinois State Police, 251 F.3d 612, 650 (7th Cir. 2001). The court assumes that the additional materials submitted by Mr. McAfee were intended for illustrative purposes.

Accepting as true Mr. McAfee's assertion that the fifteen violations alleged in his complaint weren't the only reporting violations that occurred before his surgery, Mr. McAfee still hasn't suggested how any delay in filing a report (or reports) with the FDA caused or contributed to his injuries, *i.e.*, that had Medtronic filed the report of the July 6, 2006 adverse event before his surgery, his physician would have received notice of that filing, and would have considered and used a different lead. Mr. McAfee simply alleges that the failure to file adverse reports with the FDA "proximately caused [his] injuries and damages." (Amd. Cmplt. ¶¶ 66(g) and 67). Conclusory allegations are insufficient. See Martin v. Medtronic, Inc., 32 F. Supp. 3d 1026, 1043 (D. Ariz. 2014); Hawkins v. Medtronic, Inc., 2014 WL 346622, at *8 (E.D. Cal. 2014); Eidson v. Medtronic, Inc., 981 F.Supp.2d 868, 889 (N.D. Cal. 2013). To the extent Mr. McAfee alleges that he was injured because Medtronic didn't warn physicians and their patients of adverse events (Amd. Cmplt. ¶ 29), 21 U.S.C. § 360k(a) preempts his claim. Riegel v. Medtronic, Inc., 552 U.S. 312, 321-22 (2008); Perez v. Nidek Co., Ltd., 711 F.3d 1109, 1118 (9th Cir. 2013); McMullen v. Medtronic, Inc., 421 F.3d 482, 488 (7th Cir. 2005); Martin v. Medtronic, Inc., 32 F. Supp. 3d at 1043.

B.

Although Medtronic didn't base its motion to reconsider on the argument raised in footnote 1 of its brief, it also contends that the court erred as a matter of law when it concluded that Mr. McAfee's failure to warn claims "would not impose state-law requirements 'different from, or in addition to,' those imposed by

the FDA during the premarket approval process,” and assumed that Indiana law would recognize a failure-to-warn claim based on Medtronic’s alleged failure to submit timely adverse event reports to the FDA.

The express preemption provision in the Medical Device Act precludes claims based on a state requirement “which is different from, or in addition to, any requirement applicable . . . to the device” under federal law, 21 U.S.C. § 360k(a); Riegel v. Medtronic, Inc., 552 U.S. at 321. It doesn’t apply to a “parallel” claim. Id. at 330.

To state a parallel claim and avoid preemption, Mr. McAfee must show that Indiana law imposes a requirement or duty that is “genuinely equivalent” to the federal reporting requirements that were allegedly violated. See Bates v. Dow Agrosciences LLC, 544 U.S. 431, 454 (2005); Wolicki-Gables v. Arrow Int’l, Inc., 634 F.3d 1296, 1300-01 (11th Cir. 2011); McMullen v. Medtronic, Inc., 421 F.3d at 489. “State and federal requirements are not genuinely equivalent if a manufacturer could be held liable under the state law without having violated the federal law.” McMullen v. Medtronic, Inc., 421 F.3d at 489.

The court assumed for purposes of the motion to dismiss that Mr. McAfee had sufficiently alleged a parallel claim because the parties didn’t address the issue of whether a warning to a third party, like the FDA, would satisfy a manufacturer’s duty to warn the user or consumer of latent dangers associated with the lead under Indiana law, specifically IND. CODE §§ 34-20-2-2 and 34-20-4-2 (the state statutes on which Mr. McAfee based his claims). McAfee v. Medtronic,

Inc., No. 1:12cv417, 2015 WL 3617755, * 5 (N.D. Ind. June 4, 2015). The authorities Medtronic cites in footnote 1 of its brief in support of the motion to reconsider don't cure the problem.

III. CONCLUSION

For the foregoing reasons, Medtronic's motion for reconsideration [Doc. No. 32] is GRANTED, and the state law claims based on a failure to warn are DISMISSED, without prejudice. Pursuant to Fed. R. Civ. P. 15(a)(2), Mr. McAfee is afforded to and including May 26 to file an amended complaint, if appropriate.

SO ORDERED.

ENTERED: May 5, 2016

/s/ Robert L. Miller, Jr.
Judge, United States District Court